JS 44C/SDNY
REV. 12/2005

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

PLAINTIFFS
SHIRLEY LINEBERRY

DEFENDANTS
PROCTER & GAMBLE PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Valad & Vecchione, PLLC 3863 Plaza Drive
Fairfax, VA 22030 (730) 352-4800

ATTORNEYS (IF KNOWN)

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)
Diversity, 28 U.S.C. § 1332. This case should properly be assigned to Judge Keenan.

Has this or a similar case been previously filed in SDNY at any time? No [X] Yes? [ ] Judge Previously Assigned

If yes, was this case Vol. [ ] Invol. [ ] Dismissed. No [ ] Yes [ ] If yes, give date _____ & Case No. _____

(PLACE AN [x] IN ONE BOX ONLY)

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Check if demanded in complaint:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.? IF SO, STATE:

DEMAND $ > 75,000.00 OTHER _____ JUDGE _____ DOCKET NUMBER _____

Check YES only if demanded in complaint
JURY DEMAND: [X] YES [ ] NO

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.

(SEE REVERSE)

(PLACE AN x IN ONE BOX ONLY) **ORIGIN**

☒ 1 Original Proceeding ☐ 2a. Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from (Specify District) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judge Judgment

☐ 2b. Removed from State Court **AND** at least one party is a pro se litigant

(PLACE AN x IN ONE BOX ONLY) **BASIS OF JURISDICTION** ***IF DIVERSITY, INDICATE CITIZENSHIP BELOW. (28 USC 1332, 1441)***

☐ 1 U.S. PLAINTIFF ☐ 2 U.S. DEFENDANT ☐ 3 FEDERAL QUESTION (U.S. NOT A PARTY) ☒ 4 DIVERSITY

CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(Place an [X] in one box for Plaintiff and one box for Defendant)

	PTF	DEF		PTF	DEF		PTF	DEF
CITIZEN OF THIS STATE	[ ] 1	[ ] 1	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	[ ] 3	[ ] 3	INCORPORATED and PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE	[ ] 5	[x] 5
CITIZEN OF ANOTHER STATE	[x] 2	[ ] 2	INCORPORATED or PRINCIPAL PLACE OF BUSINESS IN THIS STATE	[ ] 4	[ ] 4	FOREIGN NATION	[ ] 6	[ ] 6

PLAINTIFF(S) ADDRESS(ES) AND COUNTY(IES)

SHIRLEY LINEBERRY,
15021 Aiken Road
Wake Forest, North Carolina 27587
Wake County

DEFENDANT(S) ADDRESS(ES) AND COUNTY(IES)

PROCTER & GAMBLE PHARMACEUTICALS, INC.
One Proctor Gamble Plaza
Cincinnati, Ohio 45202
Hamilton County

AVENTIS PHARMACEUTICALS, INC.
200 Crossing Boulevard
Bridgewater, New Jersey 08807
Somerset County

DEFENDANT(S) ADDRESS UNKNOWN

REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:

Check one: THIS ACTION SHOULD BE ASSIGNED TO: ☐ WHITE PLAINS ☒ FOLEY SQUARE
(DO NOT check either box if this a PRISONER PETITION.)

DATE 10/11/2007 SIGNATURE OF ATTORNEY OF RECORD

RECEIPT #

ADMITTED TO PRACTICE IN THIS DISTRICT
[ ] NO
[x] YES (DATE ADMITTED Mo. _____ Yr. _____)
Attorney Bar Code #

Magistrate Judge is to be designated by the Clerk of the Court.

Magistrate Judge _____ is so Designated.

J Michael McMahon, Clerk of Court by _____ Deputy Clerk, DATED _____.

UNITED STATES DISTRICT COURT (NEW YORK SOUTHERN)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SHIRLEY LINEBERRY,
15021 Aiken Road
Wake Forest, North Carolina 27587,

PLAINTIFF,

v.

PROCTER & GAMBLE PHARMACEUTICALS, INC.,
One Proctor Gamble Plaza
Cincinnati, Ohio 45202,

and,

AVENTIS PHARMACEUTICALS, INC.,
200 Crossing Boulevard
Bridgewater, New Jersey 08807,

DEFENDANTS.

C.A. No. _____

JURY DEMANDED

COMPLAINT AND JURY DEMAND

NOW COMES Plaintiff, Shirley Lineberry ("Mrs. Lineberry" or "Plaintiff"), by and through counsel, and hereby sues the defendants, Proctor & Gamble Pharmaceuticals ("P&G"), an Ohio corporation with principal offices located in Cincinnati, Ohio, and Aventis Pharmaceuticals, Inc. ("Aventis"), a Delaware Corporation with principal offices located in Bridgewater, New Jersey (collectively "Defendants"), and for her cause of action states:

I. INTRODUCTION

1. The prescription drug Actonel®, produced and marketed by P&G and Aventis, causes and precipitates osteonecrosis of the jaw, mandible or maxilla bone among patients taking those drugs. Osteonecrosis is death of a bone. Osteonecrosis of the jaw is a permanently disfiguring and extremely painful condition, and can result in the complete loss of the patient's jaw bone. Plaintiff in this action was prescribed and ingested Actonel®, and has suffered osteonecrosis of the jaw bone.

II. PARTIES

A. PLAINTIFF

2. Plaintiff Shirley Lineberry is a citizen and resident of the State of North Carolina, residing in Wake Forest, North Carolina. She was prescribed, purchased, and ingested Actonel®, and as a result thereof suffered severe osteonecrosis of the jaw. As is the case with all patients suffering from this condition, Mrs. Lineberry is at risk for needing further invasive procedures or surgeries in the future should her condition require it or should it deteriorate further.

B. DEFENDANTS

3. Defendant P&G is an Ohio corporation, with its principal place of business at One Proctor Gamble Plaza, Cincinnati, Ohio 45202.

4. Defendant Aventis is a Delaware corporation, with its principal place

of business at 200 Crossing Boulevard, Bridgewater, New Jersey 08807.

5. At all times relevant hereto, P&G and Aventis were engaged in the business of marketing, distributing, promoting, testing, labeling and/or selling the drug Actonel®. P&G and Aventis market and distribute Actonel® throughout the world, including all fifty states in the United States, and throughout the state of North Carolina.

III. JURISDICTION AND VENUE

6. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by an individual Plaintiff who is a citizen of a different state from the Defendants. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1391(c).

IV. FACTUAL BACKGROUND

7. Actonel®, chemical name risedronate sodium, is classified as a bisphosphonate and is prescribed for treatment of osteoporosis. Actonel® has been approved by the United States Food and Drug Administration.

8. Starting in 2002 or before, bisphosphonate drugs were linked to osteonecrosis of the jaw. In 2003, one physician reported in the Journal of Oral and Maxillofacial Surgery thirty-six cases of osteonecrosis of the jaw in patients who

had received the intravenous bisphosphonate drugs Aredia® or Zometa®, made by another manufacturer. In 2004, another group of physicians reported in the same journal sixty-three cases of osteonecrosis of the jaw in patients taking bisphosphonate drugs, seven of whom took oral bisphosphonates, including one who took Actonel®. As a result of this and other information, Defendants knew or should have known that bisphosphonate drugs, including Actonel®, cause osteonecrosis of the jaw.

9. Despite knowledge of the specific risk, the product literature and marketing materials prepared by Defendants and circulated to physicians and made available to patients contained no warning about the risk of development of osteonecrosis of the jaw. When large numbers of cases of osteonecrosis of the jaw began to appear in bisphosphonate users, the FDA recommended in a post-marketing review that P&G and Aventis change the Actonel® label to reflect the risk of osteonecrosis of the jaw. (Office of Drug Safety Postmarketing Safety Review, Jennie Chang, Pharm.D., August 25, 2004, at 3, available at the FDA's web site at: http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4095B2_03_04-FDA-TAB3.pdf, attached hereto as Exhibit A.) Finally, in or around September 2005, P&G and Aventis changed the label to provide some information to the medical community and consumers, however these efforts to date

by P&G and Aventis to provide notice are not adequate to provide the public and health care professionals with the information needed to understand the true risks inherent in the use of Actonel®.

10. After learning of the linkage between bisphosphonate drugs and osteonecrosis of the jaw, P&G and Aventis have failed timely to initiate studies to further investigate risks associated with the use of Actonel®.

11. Further, P&G and Aventis had a duty fully to test and evaluate Actonel® prior to its introduction to the market, to ensure that the drug was safe to use for its intended purpose. Defendants failed to satisfy this duty.

12. Because of the long "half-life" of bisphosphonate drugs in the body, the drug Actonel® remains in the bones of persons who have ingested it for at least many, many years or even permanently. For this reason, onset of osteonecrosis of the jaw or worsening of a patient's condition can occur years after use of the drug has been discontinued.

13. Plaintiff was prescribed and infused with Actonel® in the course of medical treatment and as a result of using that drug has endured severe pain and suffering, discomfort and disfiguration through osteonecrosis of the jaw. As a result of the osteonecrosis, Plaintiff suffers significant pain, difficulty in ingesting food normally, physical disfigurement, emotional distress and mental anguish, and

has had her life span shortened. Plaintiff has incurred and will continue to incur medical and health care related costs and expenses to treat her condition. Plaintiff has been severely damaged in mind and in body, her enjoyment of life has been decreased, and she has been adversely affected in her avocations, career and/or employment.

14. Defendants knew or should have known that Actonel® is a dangerously defective product which poses risks to human health, unknown and unknowable by the consuming public and medical professionals, including Plaintiff and her health care providers, unless disclosed by Defendants.

COUNT I
STRICT LIABILITY

15. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

16. Defendants were engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising and otherwise distributing Actonel® in interstate commerce, which it sold and distributed throughout the world, including the State of North Carolina.

17. Plaintiff was using Actonel® in the manner for which it was intended, or in a reasonably foreseeable manner.

18. Actonel® was expected to and did reach Plaintiff without substantial

change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised and otherwise distributed.

19. Plaintiff was not aware of, and reasonably could not have discovered, the actual dangerous nature of Actonel®.

20. Actonel® causes increased risks of osteonecrosis of the jaw upon consumption, and therefore constitutes a product unreasonably dangerous for normal use due to its defective design, defective manufacture, and the Defendants' misrepresentations and inadequate facts disclosed to the Plaintiff including, *inter alia*, the actual risk of developing osteonecrosis of the jaw and the permanent, irreversible harm associated with this disease.

21. As a direct and proximate result of Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Actonel® in interstate commerce, Plaintiff has suffered osteonecrosis of the jaw, and is at an increased risk of developing other diseases and conditions.

22. The Defendants, therefore, are strictly liable to the Plaintiff and Plaintiff is entitled to compensatory damages. Additionally, Defendants' conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of consumers. The Plaintiff therefore is entitled to punitive damages in

an amount to be proven at trial.

COUNT II
NEGLIGENCE - NEGLIGENT MANUFACTURE

23. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs.

24. It was the duty of the Defendants to use reasonable care in the manufacturing, creating, designing, testing, sterilizing, packaging, supplying, and otherwise distributing Actonel®.

25. Contrary to their duty, the Defendants failed: adequately and properly to test and inspect Actonel® so as to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured and sold; to utilize and/or implement a reasonably safe design in the manufacture of Actonel®; to manufacture Actonel® in a reasonably safe condition appropriate for the use for which it was intended.

26. Defendants manufactured and sold Actonel®, which as constituted was a hazard to Plaintiff's health. Defendants' manufacture and sale of Actonel® as constituted caused Plaintiff to suffer adverse side effects and disease.

27. Defendants were otherwise careless and negligent.

28. As a direct and proximate result of Defendants' negligent, reckless, and careless manufacturing, creating, designing, testing, labeling, sterilizing,

packaging, supplying, marketing, selling, advertising, and otherwise distributing Actonel® in interstate commerce, Plaintiff has suffered osteonecrosis of the jaw, is at an increased risk of developing other diseases and conditions, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT III
NEGLIENCE – FAILURE TO WARN

29. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs.

30. It was the duty of the Defendants to use reasonable care in the labeling, marketing, selling, advertising, and promoting of Actonel®, and to warn Plaintiff and her medical providers of the true risk of osteonecrosis of the jaw and other side effects when using Defendants' drug.

31. Contrary to its duty, the Defendants failed: adequately and properly to warn Plaintiff of the risks of serious complications and bodily harm when Actonel® is used in the manner for which it was intended; adequately and properly to warn Plaintiff of the risks of diseases when Actonel® is used in a manner for which it was intended; adequately and properly to label Actonel® so as to warn the Plaintiff of the risks of complications and disease; and adequately and properly to label Actonel® so as to warn the Plaintiff of the risks of osteonecrosis of the jaw.

32. Defendants' product Actonel® was unaccompanied by proper and adequate warnings regarding the risk of osteonecrosis of the jaw associated with the use of Defendants' product and the scope, severity and duration of such injuries.

33. Despite Defendants' failure to provide adequate warnings to protect users or consumers of Actonel®, Defendants nevertheless continued aggressively to market, promote, distribute, and sell the dangerously defective product.

34. As a result of Defendants' negligence, Plaintiff suffered injuries and damages as alleged herein.

35. As a direct and proximate result of Defendants' failure to warn, Plaintiff has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT IV
BREACH OF EXPRESS WARRANTY

36. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs.

37. Defendants expressly warranted to Plaintiff, by and through statements made by Defendants or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Actonel® was safe, effective, fit and

proper for its intended use.

38. In using Actonel®, Plaintiff and her health care providers relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.

39. As a direct and proximate result of Defendants' breaches of warranties, Plaintiff has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT V
BREACH OF IMPLIED WARRANTY

40. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs.

41. Prior to the time that Actonel® was used by Plaintiff, Defendants impliedly warranted to Plaintiff that Actonel® was of merchantable quality and safe and fit for the use for which it was intended. Plaintiff is unskilled in the research, design and manufacture of Actonel®, and reasonably relied on the skill, judgment and implied warranty of the Defendants in using Actonel®.

42. Actonel® was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put

to its intended use and would cause severe injuries to the user.

43. As a direct and proximate result of Defendants' breaches of warranties, Plaintiff has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

WHEREFORE, Plaintiff prays that this honorable Court enter judgment against Defendants, and in favor of the Plaintiff, and to award the following relief:

a. Award Plaintiff all damages allowed by law to compensate her for the physical injury, pain, suffering, emotional distress, mental anguish, physical disability and physical disfigurement and other losses which she has endured;

b. Award Plaintiff damages equal to the amount of her medical and health care costs and expenses incurred to date and in the future;

c. Award Plaintiff damages in an amount sufficient to compensate her for the likely future deterioration of her medical condition as a result of the harm she has suffered from use of Defendants' product;

d. Award Plaintiff damages equal to any amount of her lost wages and earnings;

e. Award Plaintiff punitive/exemplary damages to the extent necessary and appropriate to punish and deter the conduct complained of herein;

f. Award Plaintiff attorneys' fees and costs, plus interest, as allowed by law; and

g. Award such other and further legal and equitable relief as this honorable Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of this action.

Respectfully submitted,

VALAD & VECCHIONE, PLLC

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Attorneys for Plaintiff Shirley Lineberry

Date: October 11, 2007